| | |
|---|---|
| Zinc stearate | For use as lubricant. |

(c) The finished food-contact article, when extracted with distilled water at reflux temperature for 2 hours, using a volume-to-surface ratio of 2 milliliters of distilled water per square inch of surface tested, shall meet the following extractives limitations:

(1) Total extractives not to exceed 0.15 milligram per square inch of food-contact surface.

(2) Extracted phenol not to exceed 0.005 milligram per square inch of food-contact surface.

(3) No extracted aniline when tested by a spectrophotometric method sensitive to 0.006 milligram of aniline per-square inch of food-contact surface.

(d) In accordance with good manufacturing practice, finished molded articles containing the phenolic resins shall be thoroughly cleansed prior to their first use in contact with food.

### § 177.2415 Poly(aryletherketone) resins.

Poly(aryletherketone) resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food subject to the provisions of this section.

(a) *Identity*. For the purposes of this section, poly(aryletherketone) resins are poly(*p*-oxyphenylene *p*-oxyphenylene *p*-carboxyphenylene) resins (CAS Reg. No. 29658–26–2) produced by the polymerization of hydroquinone and 4,4′-difluorobenzophenone, and have a minimum weight-average molecular weight of 12,000, as determined by gel permeation chromatography in comparison with polystyrene standards, and a minimum mid-point glass transition temperature of 142 °C, as determined by differential scanning calorimetry.

(b) *Optional adjuvant substances*. The basic resins identified in paragraph (a) may contain optional adjuvant substances used in their production. These adjuvants may include substances described in § 174.5(d) of this chapter and the following:

| Substance | Limitations |
|---|---|
| Diphenyl sulfone | Not to exceed 0.2 percent by weight as a residual solvent in the finished basic resin. |

(c) *Extractive limitations*. The finished food contact article, when extracted at reflux temperatures for 2 hours with the following four solvents, yields in each extracting solvent net chloroform soluble extractives not to exceed 0.05 milligrams per square inch of food contact surface: Distilled water, 50 percent (by volume) ethanol in distilled water, 3 percent acetic acid in distilled water, and *n*-heptane. In testing the final food contact article, a separate test sample shall be used for each extracting solvent.

[63 FR 20315, Apr. 24, 1998]

### § 177.2420 Polyester resins, cross-linked.

Cross-linked polyester resins may be safely used as articles or components of articles intended for repeated use in contact with food, in accordance with the following prescribed conditions:

(a) The cross-linked polyester resins are produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols or epoxides listed in paragraph (a)(2) of this section, followed by copolymerization with one or more of the cross-linking agents listed in paragraph (a)(3) of this section:

(1) Acids:

Adipic.
Fatty acids, and dimers thereof, from natural sources.
Fumaric.
Isophthalic.
Maleic.
Methacrylic.
Orthophthalic.
Sebacic.
Terephthalic.
Trimellitic.

(2) Polyols and polyepoxides:

Butylene glycol.
Diethylene glycol.
2,2-Dimethyl-1,3-propanediol.
Dipropylene glycol.
Ethylene glycol.
Glycerol.
4,4′-Isopropylidenediphenol-epichlorohydrin.
Mannitol.
*a*-Methyl glucoside.

Pentaerythritol.
Polyoxypropylene ethers of 4,4′-isopropylidenediphenol (containing an average of 2–7.5 moles of propylene oxide).
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.
2,2,4-Trimethyl-1,3-pentanediol.

(3) Cross-linking agents:

Butyl acrylate.
Butyl methacrylate.
Ethyl acrylate.
Ethylhexyl acrylate.
Methyl acrylate.
Methyl methacrylate.
Styrene.
Triglycidyl isocyanurate (CAS Reg. No. 2451–62–9), for use only in coatings contacting bulk quantities of dry food of the type identified in §176.170(c) of this chapter, table 1, under type VIII.
Vinyl toluene.

(b) Optional adjuvant substances employed to facilitate the production of the resins or added thereto to impart desired technical or physical properties include the following, provided that the quantity used does not exceed that reasonably required to accomplish the intended physical or technical effect and does not exceed any limitations prescribed in this section:

| List of substances | Limitations (limits of addition expressed as percent by weight of finished resin) |
|---|---|
| 1. Inhibitors: | Total not to exceed 0.08 percent. |
| Benzoquinone | 0.01 percent. |
| *tert*-Butyl catechol. | |
| TBHQ. | |
| Di-*tert*-butyl hydroquinone. | |
| Hydroquinone. | |
| 2. Accelerators: | Total not to exceed 1.5 percent. |
| Benzyl trimethyl ammonium chloride | 0.05 percent. |
| Calcium naphthenate. | |
| Cobalt naphthenate. | |
| Copper naphthenate. | |
| *N, N*-Diethylaniline | 0.4 percent. |
| *N, N*-Dimethylaniline | Do. |
| Ethylene guanidine hydrochloride | 0.05 percent. |
| 3. Catalysts: | Total not to exceed 1.5 percent, except that methyl ethyl ketone peroxide may be used as the sole catalyst at levels not to exceed 2 percent. |
| Azo-bis-isobutyronitrile. | |
| Benzoyl peroxide. | |
| *tert*-Butyl perbenzoate. | |
| Chlorbenzoyl peroxide. | |
| Cumene hydroperoxide. | |
| Dibutyltin oxide (CAS Reg. No. 818–08–6) | For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin. |
| Dicumyl peroxide. | |
| Hydroxybutyltin oxide (CAS Reg. No. 2273–43–0) | For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin. |
| Lauroyl peroxide. | |
| *p*-Menthane hydroperoxide. | |
| Methyl ethyl ketone peroxide. | |
| Monobutyltin tris(2-ethylhexoate) (CAS Reg. No. 23850–94–4). | For use in the polycondensation reaction at levels not to exceed 0.2 percent of the polyester resin. |
| 4. Solvents for inhibitors, accelerators, and catalysts: | |
| Butyl benzyl phthalate (containing not more than 1.0 percent by weight of dibenzyl phthalate). | |
| Dibutyl phthalate. | |
| Diethylene glycol | As a solvent for benzyl trimethyl ammonium chloride or ethylene guanidine hydrochloride only. |
| Dimethyl phthalate. | |
| Methyl alcohol. | |
| Styrene. | |
| Triphenyl phosphate. | |
| 5. Reinforcements: | |
| Asbestos. | |
| Glass fiber. | |
| Polyester fiber produced by the condensation of one or more of the acids listed in paragraph (a)(1) of this section with one or more of the alcohols listed in paragraph (a)(2) of this section. | |
| 6. Miscellaneous materials: | |
| Castor oil, hydrogenated. | |
| α-Methylstyrene. | |

| List of substances | Limitations (limits of addition expressed as percent by weight of finished resin) |
|---|---|
| Polyethylene glycol 6000. | |
| Silicon dioxide. | |
| Wax, petroleum | Complying with § 178.3710 of this chapter. |

(c) The cross-linked polyester resins, with or without the optional substances described in paragraph (b) of this section, and in the finished form in which they are to contact food, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of their intended use, as determined from tables 1 and 2 of § 176.170(c) of this chapter, shall meet the following extractives limitations:

(1) Net chloroform-soluble extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is water or 8 or 50 percent alcohol.

(2) Total nonvolatile extractives not to exceed 0.1 milligram per square inch of food-contact surface tested when the prescribed food-simulating solvent is heptane.

(d) In accordance with good manufacturing practice, finished articles containing the cross-linked polyester resins shall be thoroughly cleansed prior to their first use in contact with food.

[42 FR 14572, Mar. 15, 1977, as amended at 48 FR 37618, Aug. 19, 1983; 54 FR 48858, Nov. 28, 1989]

### § 177.2430 Polyether resins, chlorinated.

Chlorinated polyether resins may be safely used as articles or components of articles intended for repeated use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the following prescribed conditions:

(a) The chlorinated polyether resins are produced by the catalytic polymerization of 3,3-bis(chloromethyl)-oxetane, and shall contain not more than 2 percent residual monomer.

(b) In accordance with good manufacturing practice, finished articles containing the chlorinated polyether resins shall be thoroughly cleansed prior to their first use in contact with food.

### § 177.2440 Polyethersulfone resins.

Polyethersulfone resins identified in paragraph (a) of this section may be safely used as articles or components of articles intended for repeated use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, polyethersulfone resins are:

(1) Poly(oxy-*p*-phenylenesulfonyl-*p*-phenylene) resins (CAS Reg. No. 25667–42–9), which have a minimum number average molecular weight of 16,000.

(2) 1,1′-sulfonylbis[4-chlorobenzene] polymer with 4,4′-(1-methylethylidene)bis[phenol] (maximum 8 percent) and 4,4′-sulfonylbis[phenol] (minimum 92 percent) (CAS Reg. No. 88285–91–0), which have a minimum number average molecular weight of 26,000.

(3) In paragraphs (a)(1) and (a)(2) of this section, the minimum number average molecular weight is determined by reduced viscosity in dimethyl formamide in accordance with ASTM method D2857–70 (Reapproved 1977), ''Standard Test Method for Dilute Solution Viscosity of Polymers,'' which is incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(b) The basic resins identified in paragraphs (a)(1) and (a)(2) of this section may contain optional adjuvant